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Attorney Docket No.: P-4595-US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): STEINER, Mitchell S. et al. Examiner: Not yet known.
Serial No.: 10/747,691 Group Art Unit: 1615
Filed: December 30, 2003
Title: METHODS FOR TREATING HOT FLASHES AND GYNECOMASTIA

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

1. ☐ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☒ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. 10/305,363, filed November 27, 2003 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☐ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;

APPLICANTS: STEINER, Mitchell S. et al.
SERIAL NO.: 10/747,691
FILED: December 30, 2003
Page 2

4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

- I) ☒ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or
- II) ☐ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to

APPLICANTS: STEINER, Mitchell S. et al.
SERIAL NO.: 10/747,691
FILED: December 30, 2003
Page 3

the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

2. ☐ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 05-0649.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

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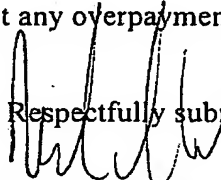
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 05-0649.

APPLICANTS: STEINER, Mitchell S. et al.
SERIAL NO : 10/747,691
FILED: December 30, 2003
Page 4

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 05-0649.

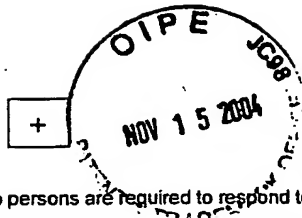

Respectfully submitted,

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Dated: October 31, 2004

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| | | Application Number | 10/747,691 | |
| | | Filing Date | December 30, 2003 | |
| | | First Named Inventor | STEINER, Mitchell S. | |
| | | Group Art Unit | | |
| | | Examiner Name | | |
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| | H | O'Brien Frank M. et al "Insulin-like Growth Fact I and Prostate Cancer", 2001 Elsevier Science Inc, Urology 58:1-7, 2001 | <input type="checkbox"/> |
| | I | Horwitz Eric M. et al "Subset Analysis of RTOG 85031 and 86-10 Indicates An Advantage For Long-Term vs. Short-Terms Adjuvant Hormones For Patients With Locally Advanced Nonmetastatic Prostate Cancer Treated with Radiation Therapy", Int. J. Radiation Oncology Biol. Phys. Vol. 49, No. 4 pp. 947-956, 2001, Elsevier Science Inc. | <input type="checkbox"/> |
| | J | Messing Edward M. et al "Immediate Hormonal Therapy Compared With Observation After Radical Prostatectomy and Pelvic Lymphadenectomy in Men With Node-Positive Prostate Cancer" The New England Journal of Medicine, 1999 Vol. 341, No. 24 | <input type="checkbox"/> |
| | K | Newling Don W.W. "Early Versus Late Androgen Deprivation Therapy in Metastatic Disease", Elsevier Science Inc, Urology 58 (supplement 2A), August 2001 | <input type="checkbox"/> |
| | L | Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998 | <input type="checkbox"/> |
| | M | Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21. | <input type="checkbox"/> |
| | N | Steger Reinhard et al. "Potential Side-Effects of Endocrine Treatment of Long Duration in Prostate Cancer" The Prostate Supplement 10:38-42, 2000 | <input type="checkbox"/> |
| | O | Goodson Max J. "Dental Applications" Vol. II, Chapter 6, | <input type="checkbox"/> |

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| Examiner Signature | | Date Considered | |
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¹ Unique citation designation number ² Applicant is to place a check mark here if English language Translation is attached

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